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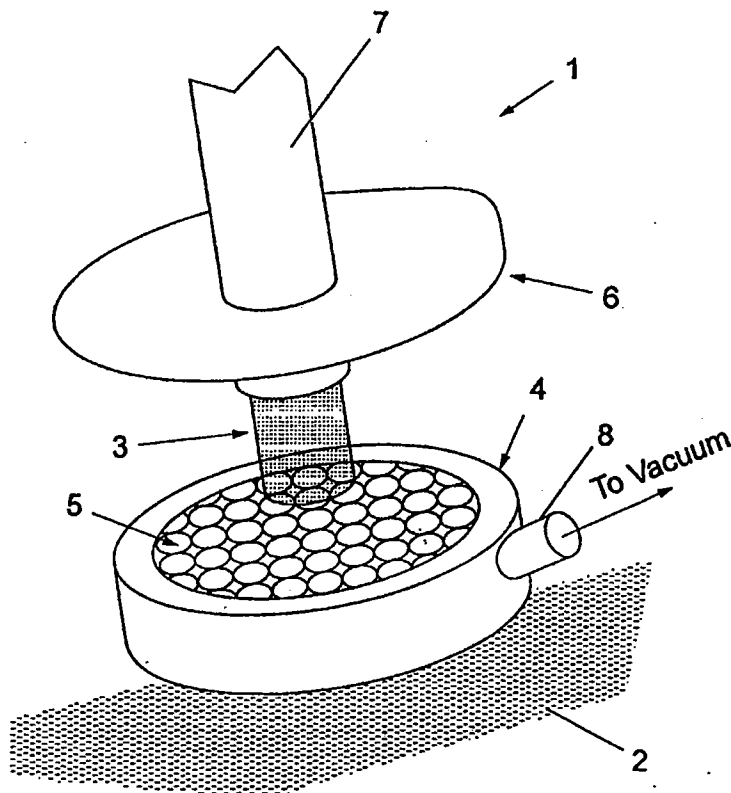
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(54) Title: APPARATUS AND METHOD FOR DELIVERY OF LIGHT TO SKIN

(57) Abstract

Improvements to a system for the process of hair removal which employs a collimated laser beam delivered to a target. These improvements include a reflector for reflecting back light scattered from the surface and improving light coupling into the tissue, use of an *array* of micro lenses for focusing the incident beam, and an annular ring to thin the epidermis and upper dermis to reduce blood volume in the illuminated area, and increase flux density at significant depths.



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1  
2 Apparatus and method for delivery of light to skin  
3

4 This invention relates to light delivery and in  
5 particular to a apparatus and method for delivery of a  
6 beam of light to a target area beneath the surface of  
7 the skin.  
8

9 Most particularly this invention relates to an.  
10 apparatus and method designed to improve the delivery  
11 of laser or other light to targets underneath the skin  
12 surface especially, but not solely, to assist in  
13 optical hair removal. That is, this invention relates  
14 to the use of optical based techniques in dermatology  
15 for the removal of unwanted stains, pigment, marks,  
16 hairs, or other sub-surface features.  
17

18 Lasers and, in some cases, other light sources have  
19 found increasing use in dermatology for the treatment  
20 or removal of sub-surface lesions. These techniques  
21 have largely been based on the concepts of selective  
22 photothermolysis. This implies that the laser  
23 wavelength is chosen to match a characteristic  
24 absorption associated with the target but not with the  
25 surrounding tissue. Thus, absorption of the laser

1 light and the subsequent heating is largely restricted  
2 to that target. In addition, the process also involves  
3 choosing the duration of the laser pulse to maximise  
4 the temperature of the target before significant  
5 conduction to the surrounding tissue can take place.  
6 For example, a 30 nanosecond pulse from a Nd:YAG laser  
7 at 1.06 $\mu$ m is strongly and selectively absorbed in the  
8 blue-black pigments of common tattoos. Since the  
9 tattoo pigments accumulate in granules of micron size,  
10 such a short pulse is almost wholly used to heat and  
11 fragment the granule before significant heating of the  
12 surroundings takes place.

13  
14 More recently techniques have been described which  
15 relate to the removal of unwanted hair using lasers.  
16 In one approach a Nd:YAG laser similar to the one  
17 mentioned above is used. Since there is little or no  
18 natural selective absorption at this wavelength, an  
19 external chromophore must first be applied and  
20 persuaded to migrate down the hair shaft to the base to  
21 provide an appropriate target.

22  
23 In an alternative approach a ruby laser at 0.694nm is  
24 used. In this approach the melanin content of the hair  
25 shaft provides the selectively absorbing chromophore.

26  
27 The ruby laser was introduced many years ago for  
28 removal of tattoos. For tattoo removal the laser  
29 output was "Q-Switched" - that is, the energy was  
30 compressed to a pulse of only a few 10's of  
31 nanoseconds. Such a pulse, whilst ideal for tattoo  
32 granule fragmentation, is neither necessary nor  
33 desirable for the more thermal process of hair removal.

34  
35 For hair removal, the ruby laser is operated in its so-  
36 called "normal mode" wherein the pulse duration is

1 extended to about 1 millisecond. The real target is  
2 not the hair itself. Following the selective  
3 absorption of the laser light along the buried hair  
4 shaft and the heating of the latter, the overall  
5 process relies on the conduction of heat from the shaft  
6 to surrounding tissue, in particular to two zones, the  
7 first near the shaft base (papilla); and the second  
8 approximately a third of the way down the shaft, known  
9 as the bulge. Direct absorption into these zones is  
10 possible, and can contribute to their heating since  
11 they also contain an enhanced level of melanin. These  
12 zones are believed to contain the cells responsible for  
13 hair growth, and damage to them via this process of  
14 laser heating should lead to permanent hair removal or  
15 at least substantially delayed regrowth.

16

17 A simple approach is to apply light with the required  
18 level of energy density to an area of skin. The level  
19 is chosen to give sufficient heating to destroy the  
20 target zones whilst leaving the surrounding tissue  
21 undamaged. In practice this required level lies  
22 between 10 and 50 J/cm<sup>2</sup>.

23

24 Various techniques have been used or proposed to assist  
25 in improving the efficiency of the process. These  
26 techniques include precooling of the area, cooling  
27 during the process, selective cooling of the epidermis  
28 using millisecond cryogen spray, use of optical  
29 transmitting gels to improve coupling into the tissue,  
30 convex shaped applicators, and devices to draw folds of  
31 skin which may receive radiation from either side.

32

33 Whereas there may be both advantages and disadvantages  
34 to varying degrees in all of these approaches, it is  
35 manifest that there is a need for a beam delivery  
36 system that addresses the problems of sub-surface

1     targeting from both an optical and a biological  
2     viewpoint.

3

4     According to a first aspect of the present invention  
5     there is provided an apparatus for delivery of a beam  
6     of light to a target area beneath the surface of the  
7     skin comprising means to deliver a collimated light  
8     beam, and light delivery means to increase the light  
9     energy density at said target area while minimising the  
10    light energy density at the surface of the skin.

11

12    Preferably said means to improve delivery comprises  
13    means to improve effective light coupling into tissue.  
14    Said means to improve effective light coupling may  
15    comprise recovery means to recover light reflected on  
16    incidence with the skin.

17

18    Said recovery means may comprise a reflective surface.

19

20    Preferably the apparatus comprises means to thin the  
21    skin above the target area. Said means may stretch the  
22    skin.

23

24    Preferably the apparatus comprises means to reduce  
25    local blood flow in the target area.

26

27    Preferably the means to stretch the skin acts also to  
28    reduce the local blood flow.

29

30    Preferably the apparatus comprises means to subject the  
31    area adjacent the target area to vacuum suction.

32

33    Said means may comprise a member adapted to be sealed  
34    to the skin and to subject the area of skin surrounding  
35    the target area to a vacuum.

36

1 Preferably said member has an annular channel. Said  
2 channel may be ring shaped or oval.

3 Preferably said channel is adapted to be positioned  
4 with the channel opening in contact with the skin.

5

6 Preferably the apparatus comprises means to increase  
7 light flux density at the depth of the target. Said  
8 means may redistribute an incident collimated beam  
9 prior to its incidence with the skin.

10

11 Said redistribution means may comprise an array of  
12 lenses. Preferably said lenses are of short focal  
13 length. Preferably said array is selected to increase  
14 the flux density at a nominated depth.

15

16 Preferably the apparatus comprises recovery means to  
17 recover light reflected on incidence with the skin;  
18 means to thin the skin above the target; and means to  
19 increase light flux at the depth of the target.

20

21 Preferably the light beam is a laser light beam.

22

23 The apparatus may further include known techniques such  
24 as tissue precooling and/or selective cooling of the  
25 epidermis and/or use of optical transmitting gels  
26 and/or convex shaped applicators and/or devices to draw  
27 folds of skin which may receive radiation from either  
28 side and/or other features already known.

29

30 According to a second aspect of the present invention  
31 there is provided a method for delivery of a beam of  
32 light to a target area beneath the surface of the skin  
33 comprising the step of using an apparatus according to  
34 the first aspect of the invention.

35

36 According to a further aspect of the present invention

1     there is provided a method for delivery of a beam of  
2     light to a target area beneath the surface of the skin  
3     comprising the steps of directing a collimated light  
4     beam onto the surface of the skin, and using a light  
5     delivery means to increase the light energy density at  
6     said target area while minimising the light energy  
7     density at the surface of the skin.

8  
9     Embodiments of the present invention will now be  
10    described by way of example only with reference to the  
11    accompanying drawings in which:

12  
13         Figure 1 shows a apparatus in accordance with an  
14         aspect of the present invention.

15  
16         Figures 2a and 2b illustrate the effect on fluence  
17         at the skin surface and at a given depth beneath  
18         the surface, of increasing the area of surface  
19         illumination of the skin;

20  
21         Figures 2c and 2d also illustrate the effect on  
22         fluence at the skin surface and at a given depth  
23         beneath the surface, of increasing the area of  
24         surface illumination;

25  
26         Figure 2e is a graphical representation of the  
27         rate of increase of the effective fluence at depth  
28         with increase of surface beam diameter;

29  
30         Figures 3a and 3b show a beam focusing  
31         arrangements in accordance with an aspect of the  
32         present invention;

33  
34         Figure 4 illustrates means for recapturing  
35         reflected light in accordance with an aspect of  
36         the present invention; and



1           Figure 5 shows an annular ring in accordance with  
2           an aspect of the present invention.

3  
4       Referring to the drawings, this apparatus, generally  
5       designated 1 is designed to provide a combination of  
6       both optical and mechanical means of improvement of the  
7       sub-surface flux density of a beam delivered by a beam  
8       delivery system to the target areas. Although this  
9       apparatus has its origins in improvements related to  
10      beam delivery for hair removal, other optical processes  
11      requiring selective sub-surface damage may benefit.

12  
13     A beam delivery system normally comprises a light  
14     source and means for its delivery to a target area. A  
15     first improvement to this system is the provision of a  
16     sealed annular ring 4 as shown in Figure 5. This  
17     annular ring is placed adjacent the tissue surface 2  
18     above the target. The region of surface skin in the  
19     annulus is subject to a vacuum by connection of a  
20     vacuum pump to vacuum outlet 8 and is thus drawn  
21     upwards to form raised areas 11. In one dimension this  
22     is similar to proposals for obtaining a fold of tissue  
23     to allow transillumination. However the instant  
24     configuration takes advantage of the fact that dermal  
25     blood is taken towards the region 11 under vacuum in  
26     the direction of arrows 10 and thus away from the  
27     central circular core area 12.

28  
29     Although the ruby laser wavelength corresponds to a  
30     minimum in the absorption spectrum of blood, residual  
31     absorption of blood remains a competing unwanted factor  
32     in the utilisation of the laser light. Thus reduction  
33     of local blood volume due to adjacent vacuum suction  
34     provides an important advantage.

35  
36     A second and more significant effect is that the

1 drawing up into the annulus of a small amount of tissue  
2 13 effectively stretches the skin 2 throughout the  
3 circular core 12. Even mild stretching of around 10%  
4 of the diameter - 2mm in Figure 5 where the central  
5 area has a diameter of 20mm - translates to a thinning  
6 of the epidermis and upper dermis of 20%. Since the  
7 reduction in light flux with depth into the skin is  
8 exponential this thinning provides an increase in flux  
9 density of as much as 80% at a depth of 3mm  
10 corresponding to the depth of the papilla. This  
11 effect, in conjunction with the reduction of the local  
12 blood volume, reduces the required incident flux  
13 density by a significant factor. These effects also  
14 improve the selectivity of the process.

15

16 This aspect of the invention is thus directed  
17 principally at providing a physical means of reducing  
18 beneficially both the blood content of the tissue  
19 immediately below the exposed area, and the thickness  
20 through which light must penetrate to reach structures  
21 at depths of several millimetres.

22

23 Both these effects, that is the biological and the  
24 physical, combine to improve the fraction of light  
25 fluence (energy per unit area) at the required depth  
26 for a given fluence at the surface.

27

28 Usually if the target structures are at some  
29 significant depth into tissue, a problem arises in  
30 trying to balance the need for a minimum fluence at  
31 depth required to effect the necessary damage, whilst  
32 sparing structures nearer the surface that normally see  
33 a significantly higher fluence. This aspect of the  
34 invention acts directly to improve this situation and  
35 thus helps in sparing surface tissue and components.

36

1 A handpiece incorporating such a ring 4 has its most  
2 immediate application in a process such as hair removal  
3 where selective damage to the follicles 2-4mm deep is  
4 required. Other applications, for example the  
5 visualisation of dermal blood vessel anatomy for  
6 diagnostic purposes would also benefit.

7  
8 The influence of light scattering in tissue is to  
9 substantially increase the volume of tissue  
10 experiencing some of the light compared with the  
11 initially exposed area. The larger the initial area,  
12 the less this affects the fluence at a given depth  
13 other than near the perimeter of the area.

14  
15 This phenomenon is best understood by reference to  
16 Figures 2a and 2b.

17  
18 In Figure 2a the spread of the energy present. in the  
19 beam, that is, the expansion of the beam due to  
20 scattering, is indicated approximately by following a  
21 line 30 representing the average direction of scattered  
22 photons. The energy incident on the surface is within  
23 an area 20 of  $1\text{mm}^2$ , but at a depth of 3mm 50% of the  
24 incident energy can be found within a much larger area  
25 21 of  $1\text{cm}^2$ . Thus the surface fluence is reduced by  
26 about a factor of 200. (This assumes that no  
27 absorption takes place.)

28  
29 If a second area 22, adjacent to the first area 20 and  
30 also of  $1\text{mm}^2$ , is illuminated with equal energy, then  
31 the fluence (energy density) on the surface remains  
32 constant. It can be seen from Figure 2b that at depth  
33 the energy from the second source in area 23 very  
34 largely overlaps that of the first source in area 21.  
35 Thus the fluence at depth has almost doubled for no  
36 change in surface fluence.

1     Figures 2c and 2d show the same effect but with sample  
2     fluences typical of laser hair removal.

3  
4     This process continues with the fraction of the surface  
5     fluence effective at depth increasing with size of  
6     illuminated area. The rate of increase slows to give a  
7     constant fraction when the illuminated area of the  
8     surface is several cm'. This function is sketched in  
9     Figure 2e, in which line 40 shows the fluence at 3mm  
10    depth (in J/cm<sup>2</sup>) plotted against the beam diameter at  
11    the surface (in mm).

12  
13    The numbers used in this example are illustrative only  
14    but are close to those encountered in skin. In the  
15    case of hair removal, a target is approximately 3 mm  
16    deep and therefore a certain level of fluence will be'  
17    required at that depth to achieve the required  
18    therapeutic effect.

19  
20    This therapeutic fluence is determined by the  
21    absorption of light from lasers such as ruby and  
22    alexandrite into the melanin within and around the  
23    follicle. The epidermis and upper dermis, however,  
24    contain the same absorbing chromophore as that present  
25    in the target. Since it is desirable to spare the  
26    epidermis and upper dermis from damage, and these occur  
27    nearer the surface, it is clear that any means by which  
28    the ratio of fluence at a depth compared with surface  
29    fluence can be increased offers an improvement in  
30    efficacy and safety.

31  
32    An approach taught in current practice is to use large  
33    areas of illumination. However this novel approach,  
34    and the second aspect of the invention, is to use a  
35    lens 15 to sharply focus the incident beam 3 to a point  
36    16 around 3 mm below the surface 2 as shown in Figure

1 3a. Although there are many scattering events as light  
2 moves through the tissue, with the consequences  
3 outlined above, each event scatters light in a  
4 predominantly forward direction. A sharply focused  
5 beam therefore offers some counteraction to the spread  
6 induced by scattering.

7  
8 Unfortunately, to focus the whole beam from a pulsed  
9 laser such as ruby or alexandrite presents a serious  
10 safety hazard; the slightest incorrect positioning of  
11 the focal point would substantially increase the  
12 coherent fluence at the surface and lead to severe  
13 damage.

14  
15 Figure 3b shows an arrangement which overcomes this  
16 disadvantage by passing the large area collimated beam  
17 3 through an array 5 of small micro lenses 5a. These  
18 lenses are of short focal length. The focusing .  
19 function of this array 5 is estimated to double the  
20 sub-surface flux at point 17. There is insufficient  
21 energy falling within the acceptance area of an  
22 individual lens 5a to present a safety hazard.

23

24 A third aspect of the invention addresses the issue of  
25 light coupling into tissue. As mentioned above, the  
26 use of a gel has been suggested as a way of improving  
27 light coupling. Since the tissue surface is  
28 microscopically uneven, applying a gel - and thus  
29 essentially smoothing the surface profile to one of  
30 near normal incidence to the beam - would indeed help  
31 to reduce the reflection losses associated with the  
32 refractive index difference between tissue and air.

33 Unfortunately this technique does not really address  
34 the reason for the 'apparent' high reflectivity of  
35 tissue.

36

1 The greater portion of the apparent reflected light is  
2 caused not by index mismatch but rather by transmission  
3 into the tissue followed by scattering into a backward  
4 direction and finally re-emergence.

5  
6 Although each scattering event is predominantly in the  
7 forward direction, there are, on average, some 200 such  
8 events per mm penetration. As described earlier some  
9 500 of the incident energy contributes to the fluence  
10 at depth whilst the remaining 50% is scattered in all  
11 the other directions. A half of this, that is 25% of  
12 the total, actually finds its way out of the tissue,  
13 contributing to the apparent reflected energy. This  
14 figure of 25% is approximate and depends on the nature  
15 of the tissue. In skin it can also vary between  
16 individuals and on sites on the same individual.  
17 However, the figure usually is between 20% and 40%.

18  
19 This aspect of-the invention seeks to provide means of  
20 capturing this effectively reflected light by using a  
21 mirror surface 6 around the handpiece 7 and thus  
22 returning the light to the tissue surface 2 once more.  
23 This is shown in Figure 4. The area of surface that is  
24 the source of this back scattered light is larger than  
25 the original illuminated area, and the emerging ray  
26 directions 18 are spread widely. Under these  
27 circumstances, only limited focusing of the light to be  
28 returned to the tissue is possible. This is achieved  
29 using a mirror surface 6 of a parabolic form. A  
30 simpler hemispherical shape or a conical section are  
31 alternatives which give adequate advantage.  
32 Irrespective of shape, the action of returning the back  
33 scattered light to the tissue surface effectively  
34 provides an increase in overall coupling, and thus a  
35 reduction in the applied energy required to reach a  
36 therapeutic level. This reduction is estimated to be

1 around 20% and therefore an initial requirement of, for  
2 example, a fluence of  $20 \text{ J/cm}^2$  at the surface 2 would be  
3 reduced to around  $16 \text{ J/cm}^2$ .

**4**

5 In summary, the embodiment shown in Figure 1 shows an  
6 apparatus 1 incorporating a combination of the  
7 improvements outlined above. This apparatus 1 includes  
8 means 4 for drawing up an annulus of tissue, thereby  
9 both stretching and thinning the central zone above a  
10 target area. This central zone is illuminated with a  
11 collimated laser beam 3 passing through an array of  
12 micro lenses 5. Typically these lenses may be 1mm in  
13 diameter and have a focal length of around 10mm. The  
14 delivery handpiece 7 is provided with a means 6 of  
15 reflecting back any scattered light returning from the  
16 tissue surface.

17

18 This embodiment incorporates all the improvements  
19 described. Each individual improvement, that is the  
20 annular ring 4, the array of micro lenses 5 and the  
21 reflector 6 may be separately applied in other simpler  
22 embodiments without detracting from their individual '  
23 novelty.

24

25 Each individual improvement may also be combined with  
26 other established methods such as tissue precooling.  
27 Other techniques, for example, for stretching the skin,  
28 would be included in the general principles outlined  
29 here.

30

31 The embodiment described above offers significant  
32 advantages to the process of hair removal with lasers  
33 , or other optical means. Specifically these include a  
34 change in the distribution of light to increase the  
35 flux density at significant depths of, for example,  
36 between 1 and 3 millimetres, a reduction in the blood

1 volume in the illuminated area and an increase in the  
2 effective light flux coupled to the skin. Thus  
3 selectivity is improved and the optical energy from the  
4 laser or other source is reduced. The embodiment shows  
5 specific means for achieving these advantages.

6

7

8 Improvements and modifications may be made to the above  
9 without departing from the scope of the invention.



## 1 CLAIMS

2 1. An apparatus for 'delivery of a beam of light to a  
3 target area beneath the surface of the skin  
4 comprising:

5  
6 a collimated light beam source; and

7  
8 light delivery means to increase the light energy  
9 density at said target area while minimising the  
10 light energy density at the surface of the skin.

11  
12 2. An apparatus as claimed in Claim 1 wherein said  
13 delivery means comprises a reflective surface  
14 adapted to recover light reflected away from the  
15 skin on incidence with the skin and to redirect  
16 said reflected light towards the skin.

17  
18 3. An apparatus as claimed in any preceding claim  
19 wherein said delivery means comprises means to  
20 stretch the skin above the target area.

21  
22 4. An apparatus as claimed in Claim 3 wherein said  
23 delivery means comprises means to subject an area  
24 of skin adjacent to the skin above the target area  
25 to vacuum suction.

26  
27 5. An apparatus as claimed in Claim 4 wherein said  
28 delivery means comprises an annular channel member  
29 adapted to be sealed to the skin.

30  
31 6. An apparatus as claimed in Claim 5 wherein said  
32 channel is ring shaped or oval or of other shape.

33  
34 7. An apparatus as claimed in Claim 5 or Claim 6  
35 wherein said channel is adapted to be positioned  
36 with the channel opening in contact with the skin.

- 1       8.    An apparatus as claimed in any preceding claim  
2            wherein 'said delivery means comprises means to  
3            redistribute an incident collimated beam prior to  
4            its incidence with the skin.  
5
- 6       9.    An apparatus as claimed in Claim 8 wherein said  
7            redistribution means comprises an array of lenses.  
8
- 9       10.   An apparatus as claimed in Claim 9 wherein said  
10           lenses are of short focal length.  
11
- 12      11.   An apparatus as claimed in Claim 9 or Claim 10  
13            wherein said array is adapted to increase the flux  
14            density at a predetermined depth.  
15
- 16      12.   An apparatus as claimed in any preceding claim  
17            wherein the light beam is a laser light beam.  
18
- 19      13.   An apparatus as claimed in any preceding claim  
20            further comprising means for precooling the tissue  
21            and/or means for selective cooling of the  
22            epidermis and/or devices to draw folds of skin  
23            which may receive radiation from either side.  
24
- 25      14.   A method for delivery of a beam of light to a  
26            target area beneath the surface of the skin  
27            comprising the step of using an apparatus  
28            according to any preceding claim.  
29
- 30      15.   A method for delivery of a beam of light to a  
31            target area beneath the surface of the skin  
32            comprising the steps of:  
33  
34            directing a collimated light beam onto the surface  
35            of the skin; and  
36

1 using a light delivery means to increase the light  
2 energy density at said target area while  
-3 minimising the light energy density at the surface  
4 of the skin.

5

6 16. A method as claimed in Claim 15 wherein a  
7 reflective surface is used to recover light  
8 reflected away from the skin on incidence with the  
9 skin and to redirect said reflected light towards  
10 the skin.

11

12 17. A method as claimed in any of Claims 15 to 16  
13 wherein the skin is stretched above the target  
14 area.

15

16 18. A method as claimed in Claim 17 wherein an area of  
17 skin adjacent to the skin above the target area is  
18 subjected to vacuum suction.

19

20 19. A method as claimed in Claim 18 wherein a vacuum  
21 member comprising an inverted annular channel is  
22 placed around the target area and the vacuum  
23 member is evacuated to draw the skin into the  
24 annular channel.

25

26 20. A method as claimed in any one of Claims 15 to 19  
27 wherein said collimated light beam is passed  
28 through an array of coplanar lenses positioned  
29 above the skin surface.

30

31 21. A method as claimed in Claim 20 wherein said  
32 lenses are microlenses of short focal length.

33

34 22. A method as claimed in Claim 20 or Claim 21  
35 wherein said array is adapted to increase the flux  
36 density at a predetermined depth below the skin

1 surface.

2

3 23. A method as claimed in Claim 22 wherein said  
4 predetermined depth is between 1 and 5 mm,  
5 preferably between 2 and 4 mm.

6

7 24. A method **as** claimed in any one of Claims 15 to 23  
8 wherein the light beam is a laser light beam.

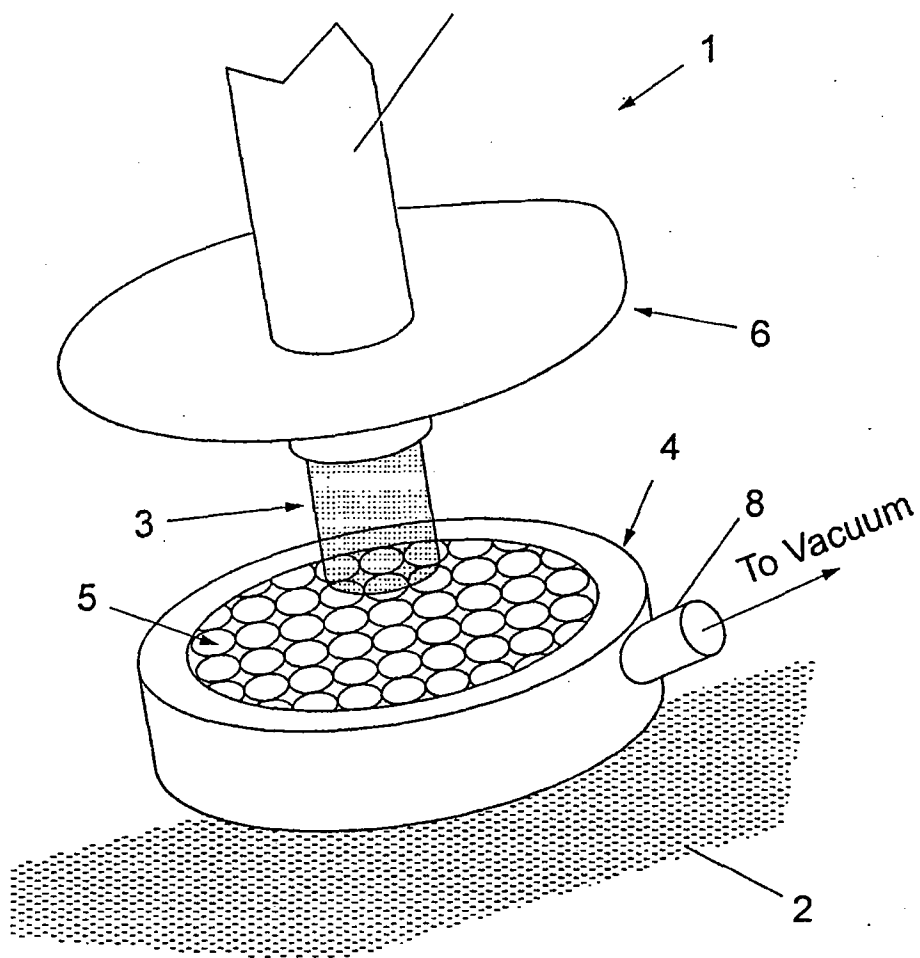
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10 25. A method as claimed in any preceding claim further  
11 comprising the steps of precooling the tissue  
12 and/or selective cooling of the epidermis and/or  
13 use of optical transmitting gels and/or use of  
14 convex shaped applicators and/or use of devices to  
15 draw folds of skin which may receive radiation  
16 from either side.

17

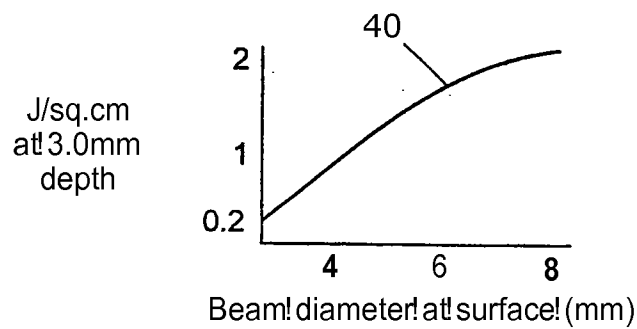
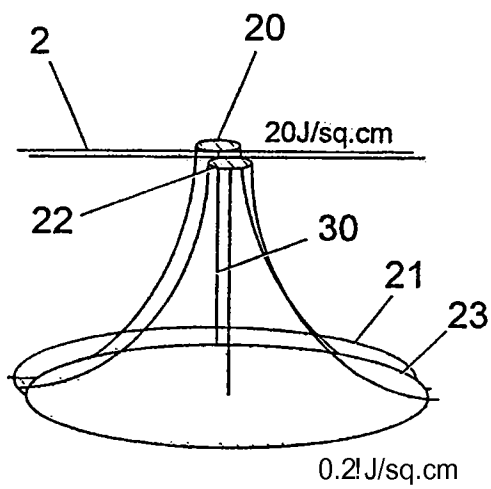
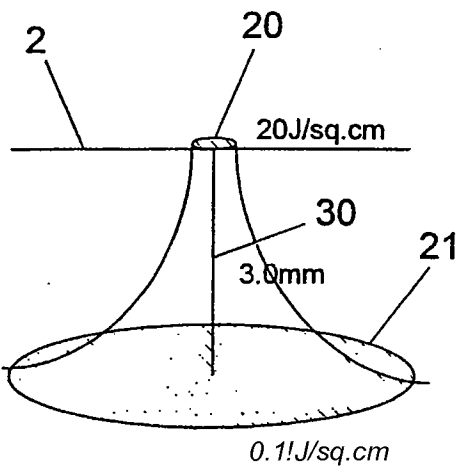
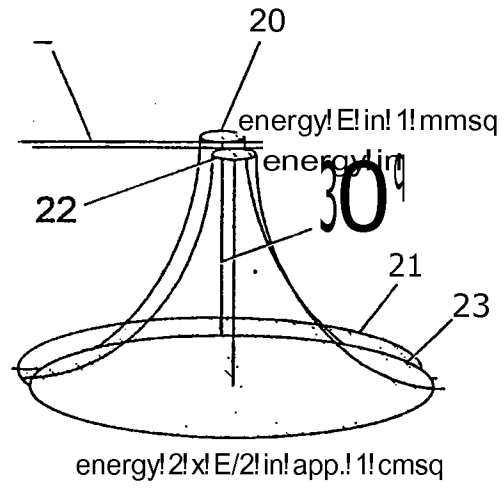
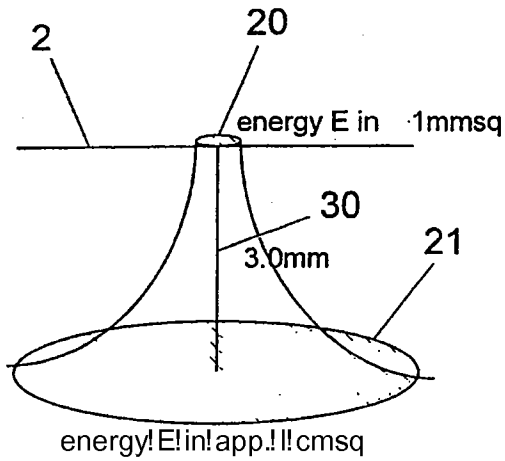
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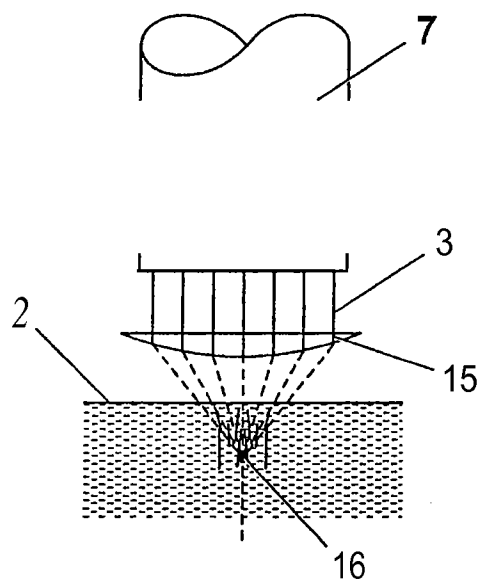


*Fig. 1*

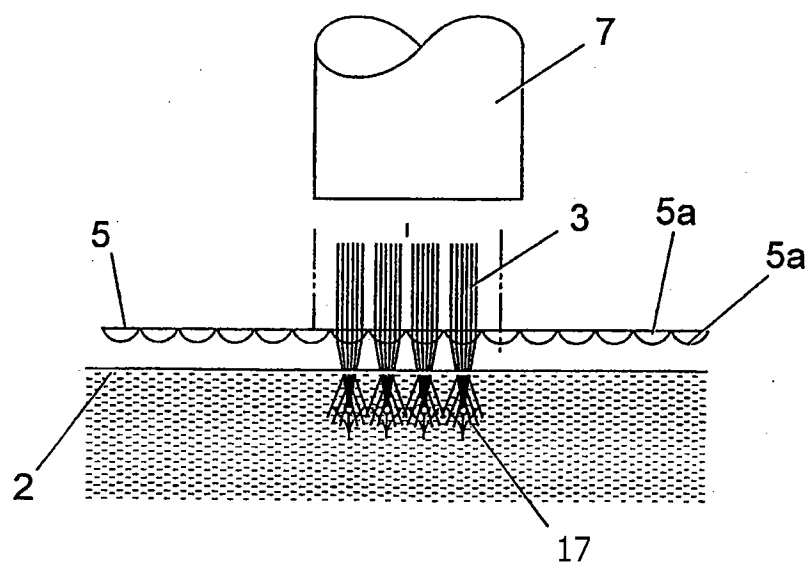
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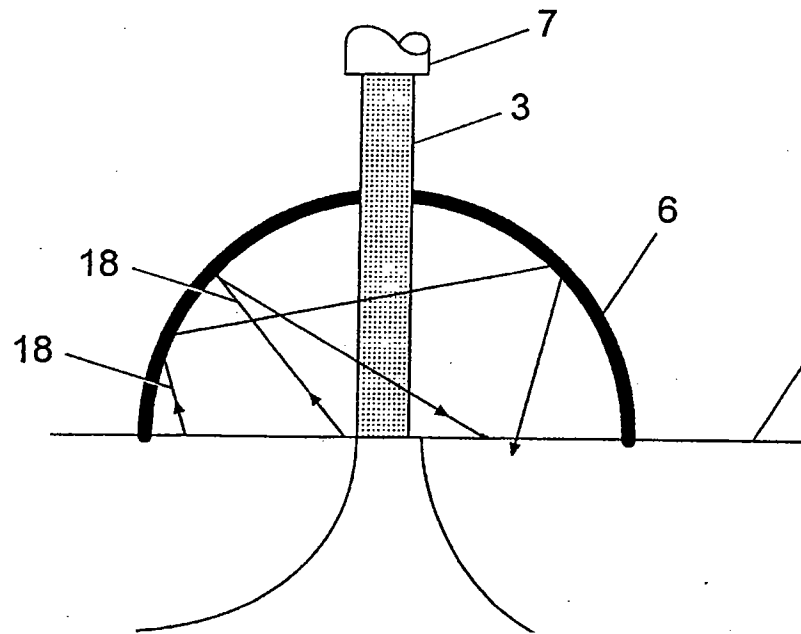


*Fig. 3a*



*Fig. 3b*

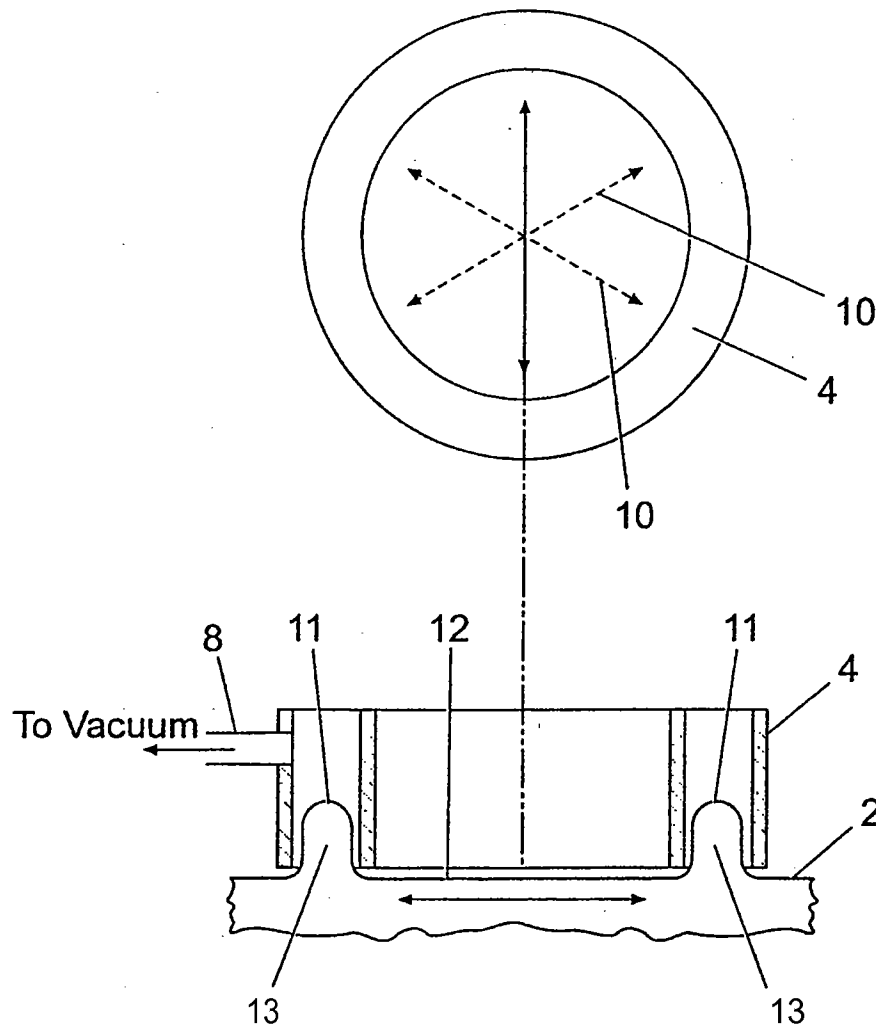
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*Fig. 4*



5/5



*Fig. 5*

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC! 6 A61B17/41		
According to International Patent Classification (IPC) or to both national classification and MO		
<b>8. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) IPC! 6 A61B A61N		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category •	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US! 5! 595! 568! A! (ANDERSON)! 21! January! 1997  see! abstract see! column! 4,! line! 50! -! column! 5,! line! 32 see! column! 4,! line! 50! -! column! 5,! line! 32 see! column! 5,! line! 63! -! column! 6,! line! 21 see! column! 6,! line! 42! -! line! 56	1-3,12, 13
X	US! 5! 546! 214! A! (BLACK)! 13! August! 1996 see! abstract	1,2
X	WO! 84! 02644! A! (WEISSMAN)! 19! July! 1984 see! abstract	1
-/--		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
• Special categories of cited documents :  'A' document defining the general state of the art which is not considered to be of particular relevance 'E' earlier document but published on or after the international filing date document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) 'O' document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the priority date claimed  'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention '%' document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone 'Y' document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art '8' document member of the same patent family		
Date of the actual completion of the international search  30! July! 1998		Date of mailing of the international search report  QS.0a <sup>2</sup>
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV New* Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer  Taccoen,! J-F

## C.Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of Comment. with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	US! 5! 735 844 A (ANDERSON) 7 April! 1998 see! abstract;! figures! 2A,2B,3B see! column! 2,! line! 6! -! line! 47 see! column! 5,! line! 21! -! column! 6,! line! 36 see! column! 14,! line! 5! -! line! 67	1-13
P,X	US! 5! 653! 706! A! (ZAVISLAN)! 5! August! 1997 see! abstract see! column! 1,! line! 31! -! line! 52	1-3

**INTERNATIONAL SEARCH REPORT**International application No .....  
**PCT/GB 98/01523****Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: **14-25**  
because they relate to subject matter not required to be searched by this Authority, namely:  
**Rule 39.1(4)**
2. ☒ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the proscribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**☐ The additional search fees were accompanied by the applicant's protest.☐ No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members,...

International Application No

**PCT/GB 98/01523**

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